



MSK.P-035-US  
PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Sadelain et al.  
Serial No.: 08/940,544  
Filed: September 30, 1997  
For: Fusion Proteins of a Single-Chain Antibody and CD28 and Uses Thereof

Examiner: L. Helms  
Art Unit: 1642

DECLARATION UNDER RULE 1.131

The undersigned declares as follows:

1. In early 1996, I was a graduate student working in the laboratory of Michel Sadelain at Sloan-Kettering Institute for Cancer Research. In early 1996, Anya Krause joined the laboratory.

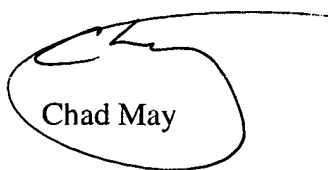
2. I remember that the first project which Anya Krause worked on was the development of single chain antibody, scFv, fusion proteins, and in particular the development of an scFv-CD28 fusion protein. I was personally present at laboratory meeting at which the results of this work were discussed, and it was reported that the scFv-CD28 fusion protein had been successfully made and that testing of the fusion protein as an artificial receptor was underway. These results were reported at meetings in the first half of 1996.

3. I have no financial interest in the above-referenced application, and am no longer affiliated with Sloan-Kettering Institute for Cancer Research.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

dated: \_\_\_\_\_

2/14/02

  
Chad May

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Art Unit: 1642

For: Fusion Proteins of a Single-Chain Antibody and CD28 and Uses Thereof

DECLARATION UNDER RULE 1.131

The undersigned declares as follows:

1. I am a named inventor of the above-referenced application, and I am familiar with the application. I have been advised that the Examiner has issued an Official Action in which the claims were rejected over art which included Alvarez-Vallina et al, Eur. J. Immunol. 26: 2304 (1996), published and WO97/34634 published 9/25/97.

2. The Alvarez-Vallina article indicates that it was accepted for publication on July 17, 1996. Therefore, it follows that the actual publication date was after this date.

3. Attached are various notebook pages relating to the conception and reduction to practice of scFv-CD28 fusion proteins of the type claimed in this application.

Exhibit A shows a page in which the concept of generating an scFv-CD28 fusion is disclosed.

Exhibit B shows a page in which a specific plan to generate an scFv-CD28 fusion is outlined. The date on the Exhibit has been obscured, but it is before July 17, 1996.

Exhibit C shows pages in which a PCR procedure amplifying CD28 is documented. The dates on the Exhibit have been obscured, but they are before July 17, 1996.

Exhibit D shows a miniprep in which the amplified CD28 440 fragment is combined with an scFv to create a fusion receptor. The date on the Exhibit has been obscured, but it is before July 17, 1996.

Exhibit E shows the first sequence results on the fusion receptor. The date on the Exhibit has been obscured, but it is before July 17, 1996.

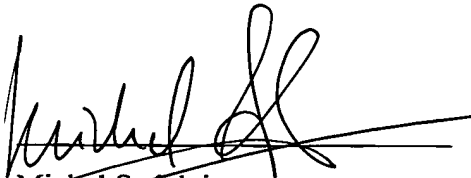
Exhibit F shows an experiment for FACS analysis of cells infected with scFv-CD28

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fusion receptor. The date on the Exhibit has been obscured, but it is before July 17, 1996.

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dated: March 5, 2002

  
Michel Sadelain